

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

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In re: BAIR HUGGER FORCED AIR  
WARMING DEVICES PRODUCTS  
LIABILITY LITIGATION

MDL No. 15-2666 (JNE/FLN)

This Document Relates To:  
All Actions

**DECLARATION OF WILLIAM T.  
RENWICK IN SUPPORT OF JOINT  
OPPOSITION OF NONPARTY  
VITAHEAT MEDICAL, LLC AND  
DEFENDANTS TO PLAINTIFFS'  
MOTION TO OVERRULE  
VITAHEAT'S RELEVANCE  
OBJECTION**

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I, WILLIAM T. RENWICK, do declare and state the following:

1. I am the Manager of Commercial Operations at VitaHEAT® Medical, Inc. (“VitaHEAT”). I have been an employee of VitaHEAT since August of 2014.
2. I submit this declaration at the request of counsel for VitaHEAT. I understand from counsel for VitaHEAT that the facts set forth in this declaration will be used in support of the Joint Opposition of Nonparty VitaHEAT Medical, LLC and Defendants to Plaintiffs’ Motion to Overrule VitaHEAT’s Relevance Objection.
3. All statements in this Declaration are based on my personal knowledge and understanding, based on information that I have acquired in my experience working at VitaHEAT, or based on information that I obtained through review of VitaHEAT records or conversations with other VitaHEAT personnel who have personal knowledge of facts and documents.

### **VitaHEAT and its UB3<sup>®</sup> System**

4. VitaHEAT is a small and relatively new startup medical device company based in Rolling Meadows, Illinois. It has eleven staff members. VitaHEAT outsources certain functions of its business to third party organizations, and has no in-house legal department or in-house counsel on staff.

5. VitaHEAT manufactures, markets and sells the VitaHEAT<sup>®</sup> UB3 Patient Warming System (“UB3” or “UB3 system”), an underbody patient warming mattress. VitaHEAT received 510(k) clearance for the early model of the UB3 system on October 4, 2013. The UB3 was first sold on the market in January 2016. The UB3 system uses patented conductive ink technology in a thin mattress design, and is the only patient warming system on the market with both battery and plug-in AC options, thus providing mobility not offered by other patient warming systems.

6. On August 31, 2016, VitaHEAT reached an agreement with 3M Company (“3M”) for 3M to serve as the exclusive distributor of the UB3 system in the United States to health system hospitals and surgery centers.

7. On information and belief, 3M manufactures and distributes a patient-warming device known as the Bair Hugger<sup>™</sup> patient warming system (“Bair Hugger” or “Bair Hugger system”) which is a convective patient warming system that uses the circulation of warm air to warm patients. The Bair Hugger system is not portable and mobile in settings where there is no electrical outlet.

8. VitaHEAT’s UB3 system differs from the Bair Hugger system in that the UB3 employs conductive warming, a different technology altogether from convective

warming. Additionally, the UB3 system can be powered by batteries, thus providing mobility not offered by the Bair Hugger system.

### **The Subpoena Requests**

9. On December 30, 2016, VitaHEAT was served with a subpoena *duces tecum* signed by attorney Gabriel Assaad of Kennedy Hodges LLP, counsel for Plaintiffs (the “Subpoena” or “VitaHEAT Subpoena”). The Subpoena contained a total of 26 requests for production of documents and required VitaHEAT to respond by January 13, 2017.

10. The Subpoena requests are extremely broad, and request the production of voluminous categories of documents and voluminous documents. For example, they seek production of all documents related to the design, testing, research, marketing, and regulatory submissions for the UB3 system. They also request production of all documents concerning the relationship and any agreements between VitaHEAT and 3M; all communications with 3M or any other medical professional, researcher, scientist, government agency, or industry organization about “patient warming generally” or the safety or efficacy of “any patient-warming device;” and documents revealing the composition and financial interests of VitaHEAT board members, among other broad categories.

### **The Burden of the Subpoena**

11. Extensive time-consuming and costly efforts would be required, both by VitaHEAT and its outside service providers, to collect the scope of materials sought by the Subpoena.

12. VitaHEAT internally houses some, but not all, of the requested categories of documents. Specifically, VitaHEAT outsources certain business functions and related data retention to third-party outside service providers with whom it has partnered for purposes of the UB3. For example, all design files and product development documents for the UB3 are housed at Keystone Manufacturing, while all quality and regulatory documents are housed at Regulatory Affairs Associates. Although both providers house these documents on behalf of VitaHEAT, VitaHEAT has access, and ultimate rights, to the documents.

13. To collect the documents sought by the Subpoena, collection efforts would be required both internally, and by each of VitaHEAT's outside service providers housing one or more responsive categories of documents.

14. Because we are a small company with a small number of employees, I would be primarily responsible for collection efforts of documents housed internally at VitaHEAT, with one or two other employees, including intermittent assistance from Chief Executive Officer Peter Farmakis and other company executives. The process of collecting these materials would likely take two to three weeks and consume nearly 100% of my time during that period, meaning that I would need to devote roughly 40 hours per week to the collection and review effort.

15. For documents housed with VitaHEAT's outside service providers, collection efforts would take place on-site at each company, and those collection costs would be shifted to VitaHEAT.

16. To collect and review all documents in VitaHEAT's control potentially responsive to the Subpoena, I estimate the total labor burden would be at least 400 man-

hours, with roughly 300 to 325 of these man-hours logged by VitaHEAT personnel and executive leadership. A small company like VitaHEAT does not have the luxury to lose roughly 27% of its workforce, over a two to three week period, to the collection and review of documents in response to a subpoena served in a lawsuit in which it is not a party.

17. The cost to VitaHEAT related to a 400 man-hour document collection effort would be significant. Applying a nominal hourly rate of \$250, a 400 man-hour document collection effort would cost approximately \$100,000. Notably, many of the personnel who would be required to assist would be executive level, commanding rates greater than \$250 per hour.

18. The non-monetary cost to VitaHEAT would likewise be an undue burden, as a document collection effort would pull personnel from their existing responsibilities in VitaHEAT's ongoing concerns as a company. In addition, as noted above, collection efforts would likely consume 100% of my time for two to three weeks, forcing me to abandon other work responsibilities entirely. As a result, VitaHEAT would likely not be able to operate internally at ordinary capacity while complying with the Subpoena.

19. Based on my review of the Subpoena and my understanding of the breadth of information maintained at VitaHEAT and accessible to VitaHEAT through its outside service providers, I estimate that collection efforts would yield a pool of at least 350,000 potentially responsive documents and ESI.

20. In order to determine which documents within this pool would be produced, the entire pool of 350,000 would have to be reviewed for responsiveness, privilege, and confidentiality, most likely with the assistance of a team of lawyers VitaHEAT would have

to retain. Based on my experience in responding to a much narrower subpoena in the past, I estimate such a review effort would cost an additional \$100,000 to \$150,000. Estimated total costs to respond to the subpoena would be \$200,000 to \$250,000.

### **Potential Competitive Harm to VitaHEAT**

21. An equally important consideration with regard to the Subpoena, aside from undue burden, is the competitive harm VitaHEAT would likely suffer to the extent its trade secret and other confidential, commercially sensitive documents were revealed to a competitor.

22. The VitaHEAT Subpoena seeks, among other things, documents related to design, testing, regulatory submissions, marketing, and distribution of the UB3 system. This includes, among other things, “full design file[s]”; efficacy, safety, and comparison testing; communications with government agencies; and marketing strategies. The Subpoena also seeks personal and financial information for VitaHEAT’s board members. These are just examples of requests that demand production of confidential, sensitive, and/or proprietary information of VitaHEAT.

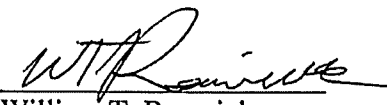
23. The Subpoena is signed by attorney Gabriel Assaad of the Kennedy Hodges law firm. I understand that Kennedy Hodges was at one time, and still may be, a lawyer for Dr. Scott Augustine, CEO of HotDog International. HotDog International manufactures a conductive-heat patient-warming device known as the HotDog, a direct competitor to UB3 in the conductive-heat patient warming market.

24. Accordingly, if VitaHEAT were to respond to the Subpoena in full, it would be producing trade secret and other highly confidential and commercially sensitive

documents to the lawyers for one of its chief competitors. The UB3 conductive ink technology is new and considered next-generation in patient warming solutions. Furthermore, VitaHEAT's exclusive distributorship agreement with 3M contains commercially sensitive information. Were Dr. Augustine or any other conductive-heat patient-warming competitor to gain access to these highly confidential and commercially sensitive documents, they would likely gain one or more business advantages, resulting in irreparable harm to VitaHEAT.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on: February 16 2017

  
William T. Renwick